BARBARA J. EVANS

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LEGAL EDUCATION

J.D., Yale Law School, 1994
LL.M. Health Law, University of Houston, 2003
Admitted to practice: New York (since 1996), Texas (since 2000)

OTHER EDUCATION

Post-doctoral Fellow, Clinical Ethics, M.D. Anderson Cancer Center, 2003 – 2004
Ph.D., Earth Sciences, Stanford University, 1984
M.S., Applied Earth Sciences, Stanford University, 1982
B.S., Electrical Engineering, with Honors, University of Texas at Austin, 1979

CURRENT EMPLOYMENT

University of Florida, Gainesville, FL (2020 – present). Professor of Law and Stephen C. O'Connell Chair, Fredric G. Levin College of Law; Professor of Engineering, Herbert Wertheim College of Engineering.

Teaching areas. Torts. Data privacy, human-subject protections, and biomedical research regulations. Food & Drug Administration law and the regulation of clinical laboratories and medical software. Regulation of novel biotechnologies. Health law. Genomic civil rights

Research interests. Legal and ethical issues with artificial intelligence/machine learning clinical decision support and diagnostic support software. Data privacy. Financing, governance, and access to data for large-scale medical data commons and the rights of people whose data are held in medical and genomic databases. Regulatory issues with novel gene-editing technologies and genomic and other diagnostic tests. Food & Drug Administration regulatory matters, especially for medical devices. Health care law.

Publications. See pages 8-17

PRIOR EMPLOYMENT

2007 – 2020 **University of Houston**, Houston, TX
University of Houston Law Center (2007-2020), Mary Ann and Lawrence E. Faust Professor of Law (2018-2020) and Director, Center for Biotechnology & Law (2007-2020), **University of Houston Cullen College of Engineering** (2017-2020), Professor of Electrical and Computer Engineering (2017-2020). **Other affiliations within the Texas Medical**

Center. Center for Medical Ethics and Health Policy, Baylor College of Medicine, Health Policy Scholar (2016-2020), Affiliated Member (2013-present). **Previous positions at University of Houston**. Alumnae College Professor of Law (2016-2018); George Butler Research Professor (2014-2016); Professor of Law (9/2011-present); Associate Professor (1/2007-8/2011); Co-director, Health Law & Policy Institute (2007-2013).

Courses taught. U.S. Biotechnology Regulatory Framework; Regulating Disruptive Innovation; Medical Devices Law, Regulation, and Ethics (for Electrical and Computer Engineers); Hot Topics in FDA Law; Biotechnology and the Law; Health Industry Basics: Providers-Innovators-Regulators; Law and Genetics; Healthcare Access, Regulation, and Enterprise; Healthcare Finance, Organization, and Quality; and Torts.

2004 – 2007 **Indiana University**, Indianapolis, IN
Director, Program in Pharmacogenomics, Ethics, and Public Policy, Indiana University School of Medicine/Center for Bioethics (9/2004 - 5/2007, 50% commitment); **Senior Scientist** (9/2004 - 8/2006), then **Research Professor of Medicine** (9/2006 - 5/2007), **Indiana University Department of Medicine/Division of Clinical Pharmacology; Adjunct Professor of Law** (9/2004 - 8/2006), **Visiting Professor of Law** (8/2006 - 12/2006, 50% commitment to law school) **Indiana University School of Law (Indianapolis).**

Courses taught. Administrative Law; Law and Genetics

2004 – 2006 **Counsel, Medical Technology Practice Group, Baker & Daniels, L.L.P.,** Indianapolis (part-time commitment, 2004 – 2006, when our practice group moved to Epstein, Becker & Green); **Counsel, Health and Life Sciences Practice, Epstein, Becker & Green, P.C.,** Washington, D.C (part-time commitment, 1/2006 - 9/2006)

2003 – 2004 **The University of Texas M.D. Anderson Cancer Center**, Houston, TX
Post-doctoral Fellow in Clinical Ethics (9/2003 – 6/2004)

1996 – 2002 **LeBoeuf, Lamb, Greene & MacRae, L.L.P.,** New York and Moscow
Associate (5/1996 – 5/1998); **Partner** (6/1998 – 7/2001); **Of Counsel** (8/2001- 2/2002). Advised U.S., U.K., and Russian corporations on regulatory and transactional matters, including major infrastructure asset acquisitions and regulatory compliance issues. Advised governments on major legal reform projects in energy and infrastructure sectors as a prelude to privatization. Supervised the legal team for the World Bank-funded Russian Federation Electricity Sector Reform Support Project (Project 643/02/98 PDL–101) and, as subcontractor to Andersen Consulting, acted as regulatory advisor to the Kres Commission which President Putin appointed in 2000 to implement reforms in Russia's electric power sector.

1994 – 1996 **International Bank for Reconstruction and Development (The World Bank),** Washington, D.C., **Senior Energy Economist, Region IV Europe and Central Asia, Infrastructure Division** (9/1994 – 3/1996). Served as project manager or economist on World Bank lending projects to modernize energy infrastructure, address environmental problems, or provide sectoral and macroeconomic support in Region IV nations of the former Soviet Union.

1992 – 1994 **Part-time and Temporary Employment While in Yale Law School Economist**, John F. Kennedy School of Government, Harvard University, Project for Economic Reform in Ukraine, Kiev, Ukraine (full-time, 6/1992 – 8/1992). **Regulatory Consultant** under Contract No. MG498, International Bank for Reconstruction and Development (The World Bank), Washington, D.C.; Kiev, Ukraine; Vilnius, Lithuania; and Kishinov, Moldova, (part-time, 10/1992 – 8/1994). **Regulatory Consultant** under Contract No. C4220, The European Bank for Reconstruction and Development, London and Kiev, Ukraine (one short project in 1993 – 1994). **Summer Associate and Consulting Economist,** LeBoeuf, Lamb, Greene & MacRae, L.L.P., New York and Moscow (full-time, 6/1993 – 8/1993; part-time, 9/1993 – 1/1994).

Before law school - various positions as an engineer and economist in the energy industry.

GRANTS AND SPONSORED RESEARCH PROJECTS (AWARDED OR COMPLETED)

Member, Bioethics Advisory Panel, **Collaborative Research: Booting up a Mirror Cell.** National Science Foundation EF 1935372 (9/1/2019 - 8/31/2023) (Neal Devaraj, P.I.)

Member, Working Group, **Choice of Law in Precision Medicine Research,** NIH/NHGRI (Leslie Wolf and Laura Beskow, PIs) (awarded 1/2020)

Member, **Industry-University Collaborative Research Center for Building Reliable Advances and Innovations in Neurotechnology (BRAIN)**. National Science Foundation CNS-1650536 (3/2017 - 3/2022) (Jose Contreras-Vidal and Marco Santelli, PIs)

Advisory Committee Member, **Development of Recommendations and Policies for Genetic Variant Reclassification.** NIH/NHGRI R01HG010365 (Wendy Chung, M.D., Ph.D., and Paul Appelbaum M.D., P.I.s) (12/1/2018 - 11/30/2022)

Privacy Working Group Member and Co-lead, Data Quality Working Group, **LawSeq^{SM}: Building a Sound Legal Foundation for Translating Genomics into Clinical Application**. NHGRI/NCI 1R01HG008605 (Susan M. Wolf, Ellen W. Clayton, Frances Lawrenz, PIs) (06/06/16 - 5/31/19)

Sentinel System (FDA-14-RFP-1127332). Member of Privacy Panel for Harvard Pilgrim-led consortium to operate the U.S. Food & Drug Administration's Sentinel System, a very large-scale distributed pharmacoepidemiological data network. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim Health Care Institute (Richard Platt, M.D., P.I.) (2014 - 2019)

Member, Working Group, **Addressing ELSI Issues in Unregulated Health Research Using Mobile Devices**. National Cancer Institute/National Human Genome Research Institute/Office of Science Policy and Office of Behavioral and Social Sciences Research, Office of the Director, National Institutes of Health Project 1R01CA207538 (Mark Rothstein and John Wilbanks, PIs).

Advisory Committee Member, **Building the Medical Information Commons: Participant Engagement and Policy.** NIH/NHGRI R01-HG008918 (Amy McGuire & Robert Cook-Deegan, PIs) (9/14/2015 - 6/30/2018)

Governance Development for FDA-Harvard Catalyst Activities. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim/Harvard Catalyst for studies under agreement between Sentinel Coordinating Center and U.S. Food and Drug Administration (HHS223201400030I), for legal research on privacy and human-subject protection issues in public health uses of FDA's Sentinel System (2017 - 2018)

Clinical Sequencing in Cancer: Clinical, Ethical, and Technological Studies. NIH U01HG006507 (GPJ). Study of CLIA and HIPAA regulatory issues and First Amendment questions surrounding clinical investigators' disclosure of experimental genetic test results to persons participating in research. Subcontract between University of Houston (Barbara J. Evans, P.I.) and the University of Washington (Gail P. Jarvik, P.I.) (2011 - 2017)

Regulation of Gene-editing Technologies. National Academy of Sciences NAS Agreement 2000006701 (Barbara J. Evans, PI) (2016). Commissioned paper on national regulatory frameworks for human gene editing

Clinical Sequencing Exploratory Research (CSER) Centralized Support Coordinating Center - HIPAA-CLIA Supplement. NIH 3U01HG007307-02S2. Study of impacts genomic testing laboratories will experience after 2014 changes to the individual data access requirements of the HIPAA Privacy Rule. Subcontract between University of Houston (Barbara J. Evans, P.I.) and the University of Washington (Gail P. Jarvik, P.I.) (8/1/2014 - 3/31/2015)

Consultant, **Clinical Integration of Whole Genome Sequencing: A Policy Analysis**, NIH/NHGRI R01-HG006460-03 (Amy McGuire, P.I.) (2015)

Collaborator, **Thematic Study of Research with Biospecimens**, funded by the National Human Genome Research Institute with co-sponsorship of Case Western Research University and the Petrie-Flom Center at Harvard Law School (I. Glenn Cohen, Barbara Bierer, Suzanne Rivera, Holly Fernandez Lynch, co-PIs) (2015)

Commissioned Paper, **Ownership of Data from Mobile and Wearable Health Devices**, for Robert Wood Johnson Foundation Health Data Exploration Project (Kevin Patrick, M.D., M.S. P.I.) (5/2015 - 5/2016)

Member of Multidisciplinary Panel, **Reframing Consent for Research**, funded by The Greenwall Foundation (Scott Kim, M.D., Ph.D., David Wendler and Neal Dickert, M.D., Ph.D. co-PIs) (2015)

Greenwall Foundation Faculty Scholar in Bioethics. Funding for study entitled *Governance Models to Enhance the Legitimacy and Public Acceptability of Decisions to Allow Nonconsensual Use of Data Held in Large Health Data Networks* (Barbara J. Evans, P.I.) (7/1/2010 - 6/30/2013)

Mini-Sentinel II. Collaborative study by Harvard Pilgrim Healthcare Institute and the U.S. Food & Drug Administration/Duke Clinical Trials Transformation Initiative to examine randomization techniques in a very large-scale health data network. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim Health Care Institute (Richard Platt, M.D., P.I.) (2013 - 2014)

Mini-Sentinel Privacy Panel Project. Subcontract between University of Houston (Barbara J. Evans, P.I.) and Harvard Pilgrim Health Care Institute as prime contractor under Department of Health & Human Services Contract No HHSF2232009100061 (Richard Platt, MD, P.I.) (7/1/2010 - 9/30/2010)

Member of Expert Panel, **Protecting Privacy in Health Research.** NIH Proposal RC1 CA146501-01 (Fred H. Cate, P.I.) (2009 - 2012)

PROFESSIONAL AND COMMUNITY SERVICE ACTIVITIES AND AWARDS

American Law Institute (elected to membership, January 2016)

Senior Member, Institute of Electrical and Electronics Engineers (2006-present); Corresponding Member, IEEE Medical Technology Policy Committee (2006-2008); IEEE member (since engineering school)

Tau Beta Pi engineering honor society (life member)

Order of the Barons Professor of the Year Award (2016-2017)

Service Activities Related to the U.S. Food and Drug Administration

Member, Privacy Panel, U.S. Food & Drug Administration Mini-Sentinel and Sentinel System Projects (2010-2019)

Member, Planning Board for the Center for Devices and Radiological Health's National Evaluation System for Health Technology (NEST) (2016-2017)

Member, U.S. Food and Drug Administration's Sentinel System Patient Engagement Working Group (2015-2016)

Guest Scholar, U.S. Food & Drug Administration, Center for Devices and Radiological Health (August 2016)

Member, Food and Drug Law Institute, Academic Programs Committee (2013-2016)

Member, Program Committee for March 8, 2010 *FDA Sentinel Initiative Meeting Series: Legal Issues in Active Medical Product Surveillance*, convened by the Engelberg Center for Health Care Reform at the Brookings Institution under sponsorship of FDA

Other Federal Advisory Service

Participant and Lead for multidisciplinary Expert Advisory Panel convened by the U.S. Government Accountability Office (GAO) and the National Academies of Science, Engineering, and Medicine to advise on report on Artificial Intelligence in Heath Care Systems (commencing March 2020)

Participant and Lead for multidisciplinary Expert Advisory Panel convened by the U.S. Government Accountability Office (GAO) and the National Academies of Science, Engineering, and Medicine to advise on report entitled, "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning in Drug Development" (released January 2020)

Member, National Academies of Sciences, Engineering, and Medicine Standing Committee on Aerospace Medicine and the Medicine of Extreme Environments (12/2018 – 12/2021)

Appointee, National Committee on Vital and Health Statistics (2015 – 2017) and Co-chair, Privacy Subcommittee and De-Identification Working Group (2016 – 2017); participant in "Beyond HIPAA" expert working group (2019)

Member, National Heart, Lung, and Blood Advisory Council (NHLBAC) Working Group on Emerging Issues in Data Sharing (EIDS) (10/2018 – present)

Member, U.S. National Academies of Science, Engineering, and Medicine Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System (2016 – 2017)

Peer Reviewer, National Academies of Science, Engineering, and Medicine, Making the Living World Engineerable: Science, Practice, and Policy Proceedings of a Workshop (2016)

Member, Institute of Medicine Committee on Accessible and Affordable Hearing Health Care for Adults (2015 – 2016)

Participant, International Summit on Human Gene Editing, sponsored by the U.S. National Academy of Science, U.S. National Academy of Medicine, The Chinese Academy of Sciences, and The Royal Society (December 1-3, 2015)

Member, Institute of Medicine Committee on Ethics Principles and Guidelines for Health Standards for Long Duration and Exploration Spaceflights (2013 – 2014)

Peer reviewer for Institute of Medicine consensus report entitled ETHICAL AND SCIENTIFIC ISSUES IN STUDYING THE SAFETY OF APPROVED DRUGS (Ruth R. Faden & Steven N. Goodman, Co-chairs) (2012)

Member, Institute of Medicine Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (2010-2011)

Member, Oversight Task Force of U.S. Department of Health & Human Services Secretary's Advisory Committee on Genetics, Health, & Society (2007-2008)

Other Activities

Participant, White House/Stanford Medicine X Design Workshop on Engaging Participants as Partners in Research (June 2, 2016); White House Precision Medicine Initiative Summit (February 25, 2016) and White House Champions of Change in Precision Medicine meeting (July 8, 2015)

Plenary session moderator; co-lead, breakout session, Return of Results Workshop, Jackson Heart Study Coordinating Center, University of Mississippi Medical Center (Aldolfo Correa, MD, MPH, PhD, PI) (April 4, 2017)

Member, GP-Write Consortium (2016 – 2017), a multidisciplinary group of about 200 scientists and scholars in 14 nations for preparation of white paper on genome synthesis for testing in cell lines; co-lead, with bioethicist Jonathan Moreno, of the Ethics and Legal Studies Group for /GP-Write (2017); Participant and Panelist, Human Genome Project, Part II (HGP/Write) Kick-Off Meeting, Harvard Medical School (May 10, 2016)

Visiting Scholar, Center for Law, Ethics, and Applied Research (CLEAR) in Health Information, Indiana University (August 2015)

Distinguished Health Scholar, Seton Hall Law School (March 2015)

Faculty mentor, American Society of Law, Medicine, and Ethics (ASLME) Health Law Scholars Program (2015)

Member, Texas Medical Center Clinical Research Design Team (2014)

Adjunct Professor of Clinical Pharmacology, Indiana University School of Medicine (2007 – 2015) and Affiliated Investigator, IU Center for Bioethics (2009 – 2015)

Member, External Advisory Committee, Duke University Clinical and Translational Sciences Institute under NIH Clinical and Translational Sciences Award (Robert Califf, M.D., P.I.) (2008 – 2012)

Member, American Bar Association Special Committee on Bioethics and the Law (2006-2011); Liaison of ABA Administrative Law Section to the Special Committee on Bioethics (2005-2006)

Member, Legal Working Group, Health Information Security and Privacy Collaboration (HISPC) for Indiana (2006)

Peer reviewer for U.S. Agency for Healthcare Quality and Research publication entitled REGISTRIES FOR EVALUATING PATIENT OUTCOMES: A USER'S GUIDE (2013); peer reviewer, GENETICS IN MEDICINE (2013, 2016), NEW ENGLAND JOURNAL OF MEDICINE (2013), CHEST (2013); JOURNAL OF GENERAL INTERNAL MEDICINE (2013), PHARMACOEPIDEMIOLOGY & DRUG SAFETY (2011); peer reviewer for genetics-related grant proposals submitted to The Wellcome Trust Biomedical Ethics Research Fellowship Program, United Kingdom (2011 – 2012)

Member, Program Committee, *Third International Health Privacy Summit* (Georgetown Law Center, June 2013) and *First International Health Privacy Summit* (Georgetown Law Center, June, 2011)

Member, Steering Committee, UH Faculty Senate 15th Annual Scholarship and Community Conference, *Greater Houston's Health: Urban Healthcare in the 21st Century* (2013)

Program Co-chair, Greenwall Foundation Annual Meeting (May 1-2, 2013)

Health Law Scholar, ASLME/Saint Louis University Health Law Scholars Workshop (2007)

PUBLICATIONS

Written work is sorted into five categories below: law articles; book chapters and edited volumes; scientific and medical journal articles; other writing such as advisory committee reports and comments filed in regulatory proceedings; and theses and dissertation.

Law Articles

Barbara J. Evans & Ellen Wright Clayton, *Deadly Delay: The FDA's Role in America's COVID-Testing Debacle*, 130 YALE LAW JOURNAL FORUM 78-100 (2020)

Barbara J. Evans, *The Streetlight Effect: Regulating Genomics Where the Light Is*, 48 (Supp. 1) JOURNAL OF LAW, MEDICINE, AND ETHICS 105-118 (2020) (Supplement entitled, "Building a Sound Legal Foundation for Translating Genomics into Clinical Application," reporting results from the NIH-funded LawSeq℠ project)

Barbara J. Evans, *Minding the Gaps in Regulation of Do-it-Yourself Biotechnology*, in SYMPOSIUM: DEMOCRATIZING HEALTH CARE, 21 DEPAUL JOURNAL OF HEALTH CARE LAW 1 – 18 (2020) at https://via.library.depaul.edu/cgi/viewcontent.cgi?article=1380&context=jhcl

Barbara J. Evans, Gail Javitt, Ralph Hall, Megan Robertson, Pilar Ossorio, Susan M. Wolf, Thomas Morgan, and Ellen Wright Clayton, for the LawSeq Quality Working Group, *How Can Law and Policy Advance Genomic Analysis and Interpretation for Clinical Care?,* 48 (Supp.1) JOURNAL OF LAW, MEDICINE, AND ETHICS 44-68 (2020) (Supplement entitled, "Building a Sound

Legal Foundation for Translating Genomics into Clinical Application," reporting results from the NIH-funded LawSeq[SM] project)

Mark A. Rothstein, John T. Wilbanks, Laura M. Beskow, Kathleen Brelsford, Kyle B. Brothers, Megan Doerr, **Barbara J. Evans**, Catherine M. Hammack-Aviran, Michelle L. McGowan, Stacy A. Tovino, *Unregulated Health Research Using Mobile Devices: Ethical Considerations and Policy Recommendations,* 48 JOURNAL OF LAW, MEDICINE, AND ETHICS196-226 (2020) (Supplement entitled, "Unregulated Health Research Using Mobile Devices," reporting results from the NIH-funded project, Addressing ELSI Issues in Unregulated Health Research Using Mobile Devices)

Barbara J. Evans, *The Perils of Parity: Should Citizen Science and Traditional Research Follow the Same Ethical and Privacy Principles?*, 48(Supp. 1) JOURNAL OF LAW, MEDICINE, AND ETHICS 74-81 (2020) (Supplement entitled, "Unregulated Health Research Using Mobile Devices," reporting results from the NIH-funded project, Addressing ELSI Issues in Unregulated Health Research Using Mobile Devices Mobile Health Research)

Jessica L. Roberts, Alexandra L. Foulkes, Paul S. Appelbaum, Wendy K. Chung, Ellen Wright Clayton, **Barbara J. Evans**, Gary E. Marchant, *Can Clinical Genetics Laboratories be Sued for Medical Malpractice?*, 29 Annals of Health Law and Life Sciences 153-172 (2020)

Barbara J. Evans & Susan M. Wolf, *A Faustian Bargain That Imperils People's Privacy Rights and Return of Results*, 71 FLORIDA L. REV 1281-1345 (2019)

Barbara J. Evans, *The Genetic Information Nondiscrimination Act at Age 10: GINA's Controversial Assertion that Data Transparency Protects Privacy and Civil Rights*, 60 WILLIAM & MARY LAW REVIEW 2017-2109 (2019)

Ellen Wright Clayton, Barbara J. Evans, James W. Hazel & Mark A. Rothstein, *The Law of Genetic Privacy: Applications, Implications, and Limitations*, 6 J. LAW AND THE BIOSCIENCES 1-36 (2019) at https://academic.oup.com/jlb/article/6/1/1/5489401 (open access to full text via pdf link)

Amy L. McGuire, Jessica Roberts, Sean Aas, and **Barbara J. Evans**, *Who Owns the Data in a Medical Information Commons?,* 47 JOURNAL OF LAW, MEDICINE, AND ETHICS 62-69 (2019) (special issue reporting results from the NIH-funded Building the Medical Information Commons project)

Barbara J. Evans & Pilar N. Ossorio, *The Challenge of Regulating Clinical Decision Support Software After 21st Century Cures,* in SYMPOSIUM: THE 21ST CENTURY CURES ACT: A CURE FOR THE 21ST CENTURY, 44 AM. J. LAW & MED. 237-251 (2018)

Barbara J. Evans, *Barbarians at the Gate: Consumer-Driven Health Data Commons and the Transformation of Citizen Science,* Commissioned White Paper, Robert Wood Johnson Foundation-funded Health Data Exploration Project, published at 42 AMERICAN JOURNAL OF LAW & MEDICINE 651-685 (2017)

Barbara J. Evans, *Power to the People: Data Citizens in the Age of Precision Medicine.* in SYMPOSIUM: PROGNOSIS POSITIVE - THE REVOLUTIONARY IMPACT OF TECHNOLOGY ON HEALTHCARE, 19 VANDERBILT JOURNAL OF ENTERTAINMENT AND TECHNOLOGY LAW 243-265 (2017), *available at* http://www.jetlaw.org/journal-archives/volume-19/volume-19-issue-2/power-to-the-people-data-citizens-in-the-age-of-precision-medicine/

Barbara J. Evans, *The Limits of FDA's Authority to Regulate Clinical Research Involving High-Throughput Genome Sequencing*, *in* EMERGING ISSUES AND NEW FRONTIERS FOR FDA REGULATION: AN FDLI SYMPOSIUM IN PARTNERSHIP WITH HARVARD LAW SCHOOL'S PETRIE-FLOM CENTER FOR HEALTH POLICY, BIOTECHNOLOGY, AND BIOETHICS, 70 FOOD & DRUG LAW JOURNAL 259-287 (2015) *available at* http://ssrn.com/abstract=2484101

Laura M Amendola, Martha Horike-Pyne, Susan B Trinidad, Stephanie M Fullerton, Barbara J Evans, Wylie Burke and Gail P Jarvik, *Patients' Choices for Return of Exome and Genome Sequencing Results to Relatives in the Event of Their Death*, 43 JOURNAL OF LAW, MEDICINE, AND ETHICS: SPECIAL ISSUE (Susan M. Wolf, *ed.*) 476-484 (2015)

Barbara J. Evans, *Economic Regulation of Next-Generation Sequencing, in* SPECIAL ISSUE: CLINICAL INTEGRATION OF NEXT-GENERATION SEQUENCING: A POLICY ANALYSIS (Amy L. McGuire, David J. Kaufman & Margaret A. Curnutte, *eds.*), 42 JOURNAL OF LAW, MEDICINE, AND ETHICS 51-66 (2014)

Barbara J. Evans, *Sustainable Access to Data for Postmarketing Medical Product Safety Surveillance Under the Amended HIPAA Privacy Rule*, *in* SYMPOSIUM: BALANCING PRIVACY, AUTONOMY AND SCIENTIFIC PROGRESS: PATIENTS' RIGHTS AND THE USE OF ELECTRONIC MEDICAL RECORDS FOR NON-TREATMENT PURPOSES, 24 HEALTH MATRIX 11-47 (2014)

Barbara J. Evans, *The First Amendment Right to Speak About the Human Genome*, 16 U. PENN JOURNAL OF CONSTITUTIONAL LAW 549 - 636 (2014), *available at* http://ssrn.com/abstract=2219522

Barbara J. Evans, *Institutional Competence to Balance Privacy and Competing Values: The Forgotten Third Prong of HIPAA Preemption Analysis*, 46 U.C. DAVIS LAW REVIEW 1175-1230 (2013), *available at* http://lawreview.law.ucdavis.edu/issues/46/4/Articles/46-4_Evans.pdf

Barbara J. Evans, *Why the Common Rule is Hard to Amend*, *in* SYMPOSIUM: IMAGINING THE NEXT QUARTER CENTURY OF HEALTH CARE LAW, 10 INDIANA HEALTH LAW REVIEW 363-410 (2013), *available at* http://ssrn.com/abstract=2183701

Barbara J. Evans, *The Ethics of Postmarketing Observational Studies of Drug Safety Under Section 505(o)(3) of the Food, Drug, and Cosmetic Act*, 38 AMERICAN JOURNAL OF LAW & MEDICINE 577-606 (2012), *available at* http://ssrn.com/abstract=2021986

Barbara J. Evans, *Much Ado About Data Ownership*, 25 HARVARD JOURNAL OF LAW & TECHNOLOGY 69-130 (2012), *available at* http://jolt.law.harvard.edu/articles/pdf/v25/25HarvJLTech69.pdf

Barbara J. Evans, *Seven Pillars of a New Evidentiary Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era,* 85 NOTRE DAME LAW REVIEW 519-624 (2010)

Barbara J. Evans, *Authority of the Food and Drug Administration to Require Data Access and Control Use Rights in the Sentinel Data Network,* 65 FOOD & DRUG LAW JOURNAL 67-112 (2010)

Barbara J. Evans, *Congress' New Infrastructural Model of Medical Privacy,* 84 NOTRE DAME LAW REVIEW 585-654 (2009)

Barbara J. Evans, *Judicial Scrutiny of Legislative Action that Presents Bioethical Dilemmas*, 16 VIRGINIA JOURNAL OF SOCIAL POLICY & THE LAW 179-257 (2008)

Barbara J. Evans, *What Will it Take to Reap the Clinical Benefits of Pharmacogenomics?* 61 FOOD & DRUG LAW JOURNAL 753-794 (2006)

Barbara J. Evans & David A. Flockhart, *The Unfinished Business of U.S. Drug Safety Regulation,* 61 FOOD & DRUG LAW JOURNAL 45-63 (2006)

Barbara J. Evans & Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens,* 27 JOURNAL OF LEGAL MEDICINE 119-166 (2006)

Book Chapters and Edited Volumes

Barbara J. Evans & Frank Pasquale, *Product Liability Suits for FDA-Regulated AI/ML Software, in* Innovation and Protection: The Future of FDA Medical Device Regulation (I. Glenn Cohen, Nicholson Price, Timo Minssen & Carmel Shachar *eds.* 2021 forthcoming)

Barbara J. Evans, *Programming Our Genomes, Programming Ourselves: The Moral and Regulatory Limits of Self-Harm in Do-It-Yourself Gene Editing*, in Consuming Genomics (I. Glenn Cohen, Hank Greely, Nita Farahany & Carmel Shachar, eds., 2020 *forthcoming*)

Transparency in Health and Health Care in the United States: Law and Ethics (Holly Fernandez Lynch, I. Glenn Cohen, Carmel Shachar & Barbara J. Evans, *eds.* Cambridge University Press, 2019)

Barbara J. Evans, *The Interplay of Privacy and Transparency in Health Care: The HIPAA Privacy Rule as a Case Study, in* Transparency in Health and Health Care in the United States: Law and Ethics 30-43 (Cambridge University Press, 2019)

Barbara J. Evans, *Ethical Standards for Unconsented Data Use in Genomic Data Commons*, in Routledge Handbook of the Study of the Commons 294-307 (Blake Hudson, Jonathan Rosenblum & Dan Cole, *eds*. 2019)

Jim Hawkins, Barbara J. Evans & Harlan Krumholz, *Nontransparency in Electronic Health Record Systems, in* Transparency in Health and Health Care in the United States: Law and Ethics 273-286 (Cambridge University Press, 2019)

Barbara J. Evans, *Big Data and Individual Autonomy in a Crowd*, *in* Big Data, Health Law, and Bioethics 19-29 (I. Glenn Cohen, Holly Fernandez-Lynch, Urs Gasser & Effy Vayena, *eds*., Cambridge University Press, 2018)

Barbara J. Evans & Eric M. Meslin, *Biospecimens, Commercial Research, and the Elusive Public Benefit Standard*, *in* Specimen Science 107-124 (Holly Fernandez Lynch, Barbara E. Bierer, I. Glenn Cohen, & Suzanne M.Rivera, *eds*., MIT Press, 2017)

Barbara J. Evans, *Genomic Data Commons, in* Governing Medical Knowledge Commons 74-101 (Katherine Strandburg, Brett Frischmann & Michael Madison, *eds*., Cambridge University Press, 2017)

Barbara J. Evans, *Consumer Protection in Genome Sequencing*, *in* Nudging Health: Health Law and Behavioral Economics 309-320 (I. Glenn Cohen & Holly Fernandez Lynch, *eds*., Johns Hopkins Press, 2016)

Barbara J. Evans, *Governance at the Institutional and National Level*, *in* International Summit on Human Gene Editing: A Global Discussion-Commissioned Papers 39-43 (Chinese Academy of Sciences, The Royal Society, U.S. National Academy of Sciences, and U.S. National Academy of Medicine, 2015) *at:* http://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/pga_170455.pdf

Barbara J. Evans*, The Future of Prospective Medicine Under the Food and Drug Administration Amendments Act of 2007, in* FDA in the 21st Century: The Challenges of Regulating Drugs and New Technologies 92-105 (Holly Fernandez Lynch and I. Glenn Cohen, *eds*., Columbia University Press, 2015)

Barbara J. Evans, *In Search of Sound Policy on Nonconsensual Uses of Identifiable Health Data, in* Human Subjects Research Regulation: Perspectives on the Future 265-278 (I. Glenn Cohen & Holly Fernandez Lynch, *eds*., M.I.T. Press, 2014)

Barbara J. Evans, *Legal Trends Driving the Clinical Translation of Pharmacogenomics, in* Principles of Pharmacogenetics and Pharmacogenomics 81-94 (Russ B. Altman, David A. Flockhart & David B. Goldstein, *eds.*, Cambridge University Press 2012)

Barbara J. Evans*, Ethical and Privacy Issues in Pharmacogenomic Research*, *in* Pharmacogenomics: Applications to Patient Care, Second Edition 313-338 (Howard L. McLeod et al., *eds*., American College of Clinical Pharmacy 2009)

Scientific and Medical Journal Articles

Barbara J. Evans & James Hazel, *What Are Your Genomic Civil Rights?* 21 ANNUAL REVIEW OF GENOMICS AND HUMAN GENETICS (forthcoming 2021-2022) (invited review article)

Wylie Burke, Ellen Wright Clayton, Susan M. Wolf, Susan A. Berry, **Barbara J. Evans**, James P. Evans, Diane Korgiebel, Anne-Marie Laberge, Bonnie S. LeRoy, Amy L. McGuire, *Improving Recommendations for Genomic Medicine: Building an Evolutionary Process from Clinical Practice Advisory Documents to Guidelines*, 21 GENETICS IN MEDICINE 1-8 (June 4, 2019) available at https://www.nature.com/articles/s41436-019-0549-3

Barbara J. Evans, *Parsing the Line Between Professional and Citizen Science* Open Peer Commentary on Andrea Wiggins & John Wilbanks, *The Rise of Citizen Science in Health and Biomedical Research*, 19 AMERICAN JOURNAL OF BIOETHICS 15-17 (2019) (solicited commentary)

Susan M. Wolf & Barbara J. Evans, *Defending return of results and data*, 362 SCIENCE 1255-56 (December 14, 2018)

Barbara J. Evans & Harlan M. Krumholz, *People-powered data collaboratives: fueling data science with health-related experience of individuals*, 26 JOURNAL OF THE AMERICAN MEDICAL INFORMATICS ASSOCIATION 159-161 (December 20, 2018)

Susan M. Wolf & Barbara J. Evans, *Return of Results & Data to Study Participants,* 362 SCIENCE 159 – 160 (October 10, 2018)

Barbara J. Evans, *Response to Dreyfus and Sobel,* 103 AMERICAN JOURNAL OF HUMAN GENETICS 166-168 (2018) (letter response)

Barbara J. Evans, *HIPAA's individual right of access to genomic data: reconciling safety and civil rights,* 102 AMERICAN JOURNAL OF HUMAN GENETICS 5-10 (January 4, 2018)

Barbara J. Evans & Gail P. Jarvik, *Impact of HIPAA's Minimum Necessary Standard on Genomic Data Sharing*, GENETICS IN MEDICINE, published online ahead of print, Sept. 14, 2017, doi:10.1038/gim.2017.141

Barbara J. Evans, *The Evolving Ethics Challenge in Genomic Science, in* Special Issue: Gene Editing (Larry W. Thorpe, ed.), 13 A.B.A.SCI-TECH LAWYER 22-25 (2016)

Barbara J. Evans, Wylie Burke & Gail P. Jarvik, *FDA and Genomic Tests: Getting Regulation Right*, 372 NEW ENGLAND JOURNAL OF MEDICINE 2258-64 (2015)

Barbara J. Evans, Michael O. Dorschner, Wylie Burke & Gail P. Jarvik, *Regulatory Changes Raise Troubling Questions for Genomic Testing*, 16 GENETICS IN MEDICINE 799-803 (2014); doi:10.1038/gim.2014.127

Barbara J. Evans, *Mining the Human Genome after Association for Molecular Pathology v. Myriad Genetics*, 16 GENETICS IN MEDICINE 504-509 (2014); doi:10.1038/gim.2013.186

Gail P. Jarvik, Laura M. Amendola, Jonathan S. Berg, Kyle Brothers, Ellen W. Clayton, Wendy Chung, **Barbara J. Evans** *et al*., *Return of Results to Research Participants: The Floor, the*

Ceiling, and the Choices In Between, 94 AMERICAN JOURNAL OF HUMAN GENETICS 818-826 (2014)

Wylie M. Burke, Barbara J. Evans, Gail P. Jarvik, *Return of Results: Ethical and Legal Distinctions Between Research and Clinical Care*, 166C AMERICAN JOURNAL OF MEDICAL GENETICS PART C: SEMINARS IN MEDICAL GENETICS 105-111 (2014)

Barbara J. Evans, *Minimizing Liability Risks Under the ACMG Recommendations for Reporting Incidental Findings in Clinical Exome and Genome Sequencing*, 15 GENETICS IN MEDICINE 915-920 (2013)

Barbara J. Evans, *Would Patient Ownership of Health Data Improve Confidentiality?* 14 AMERICAN MEDICAL ASSOCIATION JOURNAL OF ETHICS 724-733 (September 2012) (solicited work)

Deven McGraw, Kristen Rosati & Barbara Evans, *A Policy Framework for Public Health Uses of Electronic Health Data*, 21 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 18-22 (2012)

Amy L. McGuire, Barbara J. Evans, Timothy Caulfield & Wylie Burke, *Regulating Direct-to-Consumer Personal Genome Testing,* 330 SCIENCE 181-82 (8 Oct. 2010)

Barbara J. Evans, *Establishing Clinical Utility of Pharmacogenetic Tests in the Post-FDAAA Era, 88* CLINICAL PHARMACOLOGY & THERAPEUTICS 749-751 (2010) (solicited work)

Barbara J. Evans, *Finding a Liability-Free Space in which Personalized Medicine Can Bloom,* 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 461-67 (2007**)**

Barbara J. Evans, *Distinguishing Product and Practice Regulation in Personalized Medicine,* 81 CLINICAL PHARMACOLOGY & THERAPEUTICS 288-293 (2007) (solicited work)

Barbara J. Evans, David A. Flockhart & Eric M. Meslin, *Creating Incentives for Genomics Research to Improve Targeting of Therapies,* 10 NATURE MEDICINE 1289-91 (2004)

Barbara J. Evans, *Inconsistent Regulatory Protection Under the U.S. Common Rule,* 13 CAMBRIDGE QUARTERLY OF HEALTH CARE ETHICS 366-79 (2004)

Other Writing

Barbara Evans, Comment Letter on Clinical Decision Support Software Draft Guidance for Industry and Food and Drug Administration Staff (Jan. 2, 2020), at https://www.regulations.gov/document?D=FDA-2017-D-6569-0104

Kristen Rosati, Naomi Jorgenson & Barbara Evans, Sentinel Initiative Principles and Policies: HIPAA and Common Rule Compliance in the Sentinel Initiative (2018) at https://www.sentinelinitiative.org/communications/publications/sentinel-initiative-principles-and-policies-hipaa-and-common-rule

Barbara J. Evans, *A Tale of Two Condos: HCAD's Black-box Property Valuations Hurt Homeowners*, HOUSTON CHRONICLE A17 (July 18, 2018) (Op-ed)

Member of Committee for preparation of report, NATIONAL ACADEMIES OF SCIENCE, ENGINEERING, MEDICINE FUTURE BIOTECHNOLOGY PRODUCTS AND OPPORTUNITIES TO ENHANCE CAPABILITIES OF THE BIOTECHNOLOGY REGULATORY SYSTEM (2017)

Member, GP-Write Consortium and co-lead, Ethical, Legal, and Social Issues working group for preparation of White Paper entitled, GENOME PROJECT-WRITE: A GRAND CHALLENGE USING SYNTHESIS, GENE EDITING AND OTHER TECHNOLOGIES TO UNDERSTAND, ENGINEER AND TEST LIVING SYSTEMS (November 30, 2016) at http://engineeringbiologycenter.org/wp-content/uploads/2016/12/GP-Write-WhitePaper.pdf

Member of National Medical Device Evaluation System Planning Board and co-author, THE NATIONAL EVALUATION SYSTEM FOR HEALTH TECHNOLOGY (NEST): PRIORITIES FOR EFFECTIVE EARLY IMPLEMENTATION (Duke University, Duke - Robert J. Margolis Center for Health Policy, 2016), at https://healthpolicy.duke.edu/sites/default/files/atoms/files/NEST%20Priorities%20for%20Effective%20Early%20Implementation%20September%202016_0.pdf

Member of National Medical Device Evaluation System Planning Board and co-author, BETTER EVIDENCE ON MEDICAL DEVICES: A COORDINATING CENTER FOR A 21ST CENTURY NATIONAL MEDICAL DEVICE EVALUATION SYSTEM (Duke University, Duke – Robert J. Margolis Center for Health Policy, 2016), at https://healthpolicy.duke.edu/sites/default/files/atoms/files/med-device-report-web.pdf

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON ACCESSIBLE AND AFFORDABLE HEARING HEALTH CARE FOR ADULTS, HEARING HEALTH CARE: PRIORITIES FOR IMPROVING ACCESS AND AFFORDABILITY (National Academies Press, 2016), available at https://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and

Co-author, Comments dated January 6, 2016 by Individual Members of the National Academy of Medicine Leadership Consortium for Value and Science-Driven Health Care's Clinical Effectiveness Research Innovation Collaborative (CERIC) on U.S. Department of Health and Human Services (HHS) Proposed Rule: Federal Policy for the Protection of Human Subjects (Docket HHS-OPHS-2015-0008), *available at* http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2015-0008-1427

Comments dated January 5, 2016 by Barbara J. Evans on U.S. Department of Health and Human Services (HHS) Proposed Rule: Federal Policy for the Protection of Human Subjects (Docket HHS-OPHS-2015-0008), available at http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2015-0008-1424

Platt, R., C. Dezii, B. Evans, J. Finkelstein, D. Goldmann, S. Huang, G. Meyer, H. Pierce, V. Roger, L. Savitz, and H. Selker. 2015. *Revisiting the Common Rule and continuous improvement*

in health care: A learning health system perspective. National Academy of Medicine, Washington, DC, at http://nam.edu/perspectives-2015-revisiting-the-common-rule-and-continuous-improvement-in-health-care-a-learning-health-system-perspective/

Barbara J. Evans & Gail P. Jarvik, joined by 17 genomics researchers, Public Comments filed in Dockets FDA-2011-D-0360: Framework for Regulatory Oversight of Laboratory Developed Tests; Draft Guidance, 79 Fed. Reg. 59,776 (October 3, 2014) and FDA-2011-D-0357: FDA Notification and Medical Device Reporting for Laboratory Developed Tests; Draft Guidance, 79 Fed. Reg. 59,779 (October 3, 2014*), filed February 2, 2015, available at* http://www.regulations.gov/#!documentDetail;D=FDA-2011-D-0360-0171

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON ETHICS PRINCIPLES AND GUIDELINES FOR HEALTH STANDARDS FOR LONG DURATION AND EXPLORATION SPACEFLIGHTS: HEALTH STANDARDS FOR LONG DURATION AND EXPLORATION SPACEFLIGHTS: ETHICS PRINCIPLES, RESPONSIBILITIES, AND DECISION FRAMEWORK (2014) at http://www.nap.edu/catalog.php?record_id=18576

Co-author and Workgroup Leader for report: DEVELOPING APPROACHES TO CONDUCTING RANDOMIZED TRIALS USING THE MINI-SENTINEL DISTRIBUTED DATABASE (Mini-Sentinel Operations Center and Clinical Trials Transformation Initiative, 2014) at http://mini-sentinel.org/methods/methods_development/details.aspx?ID=1049

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS (2011), available from the National Academies Press, http://www.nap.edu/catalog.php?record_id=13150

Barbara J. Evans, Human Subjects Research Protection: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators (Docket No. HHS OPHS-2011-0005, October 25, 2011), http://www.regulations.gov/#!documentDetail;D=HHS-OPHS-2011-0005-0822 (commenting on proposed amendments to 45 C.F.R. pt. 46 and 21 C.F.R. pts. 50, 56)

Kristen Rosati, Barbara Evans & Deven McGraw, HIPAA and Common Rule Compliance in the Mini-Sentinel Pilot (Mini-Sentinel Operations Center, 2010 & 2013), http://mini-sentinel.org/work_products/About_Us/HIPAA_and_CommonRuleCompliance_in_the_Mini-SentinelPilot.pdf

Barbara J. Evans, RIN 0991-AB57: Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act (Docket No. HHS-OCR-2010-0016, Sept. 10, 2010) (commenting on constitutional constraints affecting implementation of the cost-based fee for preparation and transmittal of data under section 13405(d) of the HITECH Act)

Member of Committee for preparation of report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, MEASURING POSTMARKET PERFORMANCE AND OTHER SELECT TOPICS (Theresa Wizemann, ed., 2010)

Member of Committee for preparation of workshop report: INSTITUTE OF MEDICINE, COMMITTEE ON THE PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS, BALANCING PATIENT SAFETY AND INNOVATION (Theresa Wizemann, ed., 2010)

Barbara J. Evans, Issue Brief: Appropriate Human-Subject Protections for Research Use of Sentinel System Data, in FDA SENTINEL INITIATIVE MEETING SERIES: LEGAL ISSUES IN ACTIVE MEDICAL PRODUCT SURVEILLANCE (Engelberg Center for Health Care Reform at the Brookings Institution, 2010)

Member of Oversight Task Force and contributing author, U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES, REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY (April 2008)

Evans, Barbara J., Investing in Russian Power, in Power in Eastern Europe, a Special Report of THE FINANCIAL TIMES, Issue 59, 16-18 (11 June 2001)

Theses and Dissertation

Thesis for the Degree of LL.M. in Health Law, The University of Houston Law Center (2003) (revised and published under the title Inconsistent Regulatory Protection Under the U.S. Common Rule, cited above)

Mine Capacity Utilization During Recessionary Periods: Operating Strategy for the U.S. Copper Industry. Dissertation for the Degree of Doctor of Philosophy in Earth Sciences with specialization in Mineral Economics, Stanford University (1984)

Statistical Techniques for Subsurface Reservoir Management. Thesis for the Degree of Master of Science in Applied Earth Science with specialization in Applied Hydrogeology, Stanford University (1982)

Legal Writing Award

Second Prize, Sixth Annual Student Health Law Writing Competition (2004) sponsored by Epstein, Becker & Green P.C., for LL.M. student paper, The Six Enigmas of Bioethical Jurisprudence: Why Bioethics Fails to Produce Constitutional Rights

PRESENTATIONS

Accessing Real-World Data to Evaluate Postmarket Performance of AI-enabled Clinical Decision and Diagnostic Support Software: Can the required data be accessed ethically? (Duke-Margolis Center for Health Policy Virtual Meeting (July 22, 2020)

Product Liability Risks and Defenses for FDA-Regulated AI/ML Software, Petrie-Flom Annual Conference Podcast (June 5, 2020)

Liability, Regulatory Compliance, and First Amendment Protections for Scientific Speech, American College of Medical Genetics and Genomics Annual Conference Webcast entitled "The Genetics Hotline: Responsibility and Liability When Handling Unsolicited Patient Communications" (May 20, 2020)

Panelist, *The Ethical, Legal, and Social Implications of Return of Results in Deep Phenotyping Research* (McLean Institute for Technology in Psychiatry, Harvard Medical School, May 8, 2020).

Participant, GAO Meeting on Artificial Intelligence and Health Care Services (Washington, D.C., April 1-2, 2020)

Panelist, Challenges of Regulating AI in Health Care, Symposium: The Law and Policy of Artificial Intelligence in Health Care (University of Minnesota, March 27, 2020)

Panelist, Conference/Webcast on Legal Barriers to Genomic Research and Precision Medicine (Boston, March 27, 2020)

Panelist, The Genetics Hotline: Responsibility and Liability When Handling Unsolicited Patient Communications, American College of Medical Genetics and Genomics Annual Meeting (San Antonio, March 18, 2020)

Participant, Annual Meeting of Legal Working Group on Variant Reinterpretation (Columbia Medical School, February 24, 2020)

Resolving legal, regulatory, and economic barriers to clinical translation of innovative biomedical technologies, Herbert Wertheim College of Engineering Colloquium (University of Florida, February 7, 2020)

Protecting the Rights of People Whose Data Are Used in Research: Is Anonymization of Genomic Information and Other Big Data a Fallacy?, American Health Lawyers Association, Academic Medical Centers and Teaching Hospitals Institute (Washington D.C., January 30, 2020)

Regulatory Programming for Neurotechnology Researchers, Winter Meeting, NSF-funded BRAIN Industry-University Collaborative Research Consortium (Tempe, Az., December 13, 2019)

Regulatory Structures for Access to Health Data: Privacy and the Ethics of Data Use, Ethical, Legal, and Regulatory Issues address to Computational Health Informatics students (University of Houston, November 5, 2019)

Participant, University of Houston NSF I/U CRC BRAIN Center Roadmap Meeting (Houston, September 30, 2019)

Participant and Lead, Expert Meeting on AI in Drug Discovery and Development convened by , U.S. Government Accountability Office and National Academies of Science, Engineering, and Medicine (Boston, July 18-19, 2019)

Panelist, Roundtable on Balancing Privacy with Health Data Access, U.S. Department of Health & Human Services (Washington, D.C., July 15, 2019)

Co-reporter, Regulatory & Legal Working Group, National Institutes of Health, *All of Us* Research Program Ethical, Legal, and Social Issues Workshop (Rockville, Md., June 24-25, 2019)

Adequacy of Existing Regulatory Structures for Health Data: The Law and Ethics of Unconsented Data Use, Multidisciplinary Workshop on the Future of Health Data, sponsored by Media Freedom & Information Access Clinic and Information Society Project, Yale Law School and the Collaboration for Research Integrity and Transparency of Yale School of Medicine and Yale School of Public Health (June 13, 2019)

Panelist and Speaker, Results of the NIH LawSeq Project. ASLME 2019 Health Law Professor's Conference (Chicago, June 6, 2019)

Participant, University of Houston – Baylor College of Medicine Workshop on Data Analytics: Applications to Health-Related Research (Houston, May 23, 2019)

Programming the Genome, Programming Ourselves. Petrie-Flom Annual Conference on Consuming Genomics, Harvard Law School (May 17, 2019)

Balancing Stakeholder and Developer Needs: Challenges in FDA Regulation of Machine Learning Medical Software. Duke University/Greenwall Foundation Conference on AI in Healthcare (Washington, D.C., May 13, 2019)

Moderator, Panel on Genomic Data Quality. University of Minnesota Consortium on Law and Values in Health, the Environment, and the Life Sciences, National Conference/Webcast on Law, Policy, and Genomic Medicine (Minneapolis, April 25, 2019)

Individual Access as a Foundational Data Privacy Right, University of Minnesota Consortium on Law and Values in Health, the Environment, and the Life Sciences, National Conference/Webcast on Law, Policy, and Genomic Medicine (Minneapolis, April 25, 2019)

Expert Panelist, "Beyond HIPAA" Actions Working Session, National Committee for Vital and Health Statistics, Subcommittee on Privacy, Confidentiality, and Security (Silver Spring, Md., March 21, 2019)

Democratizing Medicine in a Tech-Driven World, Jaharis 2019 Symposium on Health and Intellectual Property Law, DePaul Law School (Chicago, March 14, 2019)
Expert Advisory Committee Member, Legal and Regulatory Issues in Genetic Variant Interpretation, Columbia University School of Medicine (February 15, 2019)

Individual Data Access as a Civil Right, Law and Biomedicine Colloquium, The Center for Law and Biomedical Sciences, University of Utah S.J. Quinney College of Law (February 13, 2019)

Participant, National Academies of Sciences, Engineering, and Medicine Standing Committee on Aerospace Medicine and the Medicine of Extreme Environments Meeting (Washington, D.C., December 13-14, 2018)

Panelist, The Need for New Regulation: Privacy Law, the FDA, and Beyond, Information Society Project & the Solomon Center for Health Law and Policy at Yale Law School, The Law & Policy of Robotics & Telemedicine in Health Care, New Haven (November 2, 2018)

Panelist, Data Privacy, New York Academy of Sciences, Healthcare in the Era of Big Data: Opportunities and Challenges (October 24-25, 2018)

Panelist (with Dr. Erika Petersen), Privacy Concerns in *New Paradigms for Neuromodulation with Downloadable Data*, Congress of Neurological Surgeons' Annual Meeting, Houston (October 6, 2018).

Redoubling Our Efforts to Protect Research Participants' Privacy Rights, National Heart, Lung, and Blood, Institute Workshop: Defining the NHLBI's research priorities in the ethical, legal, and social implications (ELSI) of genomics (September 12-13, 2018)

Ethical and Financial Implications of Patient Data Ownership, National Academy of Medicine Digital Learning Collaborative, Patient Ownership of Health Data: Implications for a Learning Health System (June 27-28, 2018)

The Genomic Glass House: Data Sharing, Individual Data Access, and Civil Rights, Opening Plenary Address, Curating the Clinical Genome 2018 Conference, Wellcome Genome Campus Conference Center, Cambridge University (May 23, 2018)

Participant and Speaker, Health Data, AI, and Health Informatics Workshop, Frontiers e.g., Carmel (May 2, 2018)

FDA Regulation of Mobile Health Apps, Addressing ELSI Issues in Unregulated Health Research Using Mobile Devices Project, Working Group Meeting #2, Chicago (April 24, 2018)

Participant, Land Trusts for Data Governance, Sage Assembly 2018: Algorithms and the Role of the Individual, Seattle *(*April 20, 2018)

The Ethics of Unconsented Data Use and other Big Data Bioethics Oxymorons, National

Academy of Science, Engineering, and Medicine Committee for Science, Technology, and Law, 2018 Meeting, California Institute of Technology (March 15, 2018)

The Challenge of Regulating Clinical Decision Support Software After 21st Century Cures, American Journal of Law & Medicine Symposium: The 21st Century Cures Act: A Cure for the 21st Century, Boston University (January 26, 2018)

Regulating Advanced Neurotech Brain/Computer Interfaces, National Science Foundation Industry/University Collaborative Research Center, Building Reliable Advances and Innovation in Neurotechnolog (BRAIN) Project, Arizona State University (December 8, 2017)

Understanding Genomic Data Access as a Civil Right, Symposium: Refining Privacy to Improve Health Outcomes, Triangle Privacy Research Hub/Duke University/University of North Carolina, (October 25-26, 2017)

Research Data, Clinical Data, Your Data: Individual Data Access as a Civil Right, Symposium: All Data is Health Data, Indiana University McKinney School of Law (October 20, 2017)

Regulatory Alternatives for In Vivo Somatic Gene Editing Products Using CRISPR-Cas9 RNA-Protein Complexes, MedGen Seminar, University of Washington, Division of Medical Genetics (June 16, 2017)

Individual Data Access Rights, Patients as Partners in Research, Broad Institute of Harvard/MIT, the Biden Cancer Initiative, and the Emerson Collective (June 12-13, 2017)

Special Regulatory Session: Regulatory Alternatives for Human Gene Editing, American Society of Gene and Cell Therapies Annual Convention, Washington (May 11, 2017)

Opening plenary address on Ethical and Legal Frameworks for GP-Write and *closing remarks on Working Group Roadmap: Ethical, Legal, and Social Issues,* GP-Write Annual Meeting, NYU Langone Medical Center (May 9-10, 2017)

Current Regulatory Frameworks for Biotechnology Products, Congressional Research Service Disruptive Technology Series Session for Members of Congress and Congressional Staff: Advances in Gene Editing – Balancing Promise and Risk (April 28, 2017)

Regulatory Alternatives for Human Genome Surgery (presentation with Dr. Bruce Conklin), BioLawLaPalooza Conference, Stanford University (April 20, 2017)

Consumer-driven Data Commons and the Transformation of Citizen Science, Benjamin N. Cardozo School of Law Intellectual Property + Information Law Symposium (March 20, 2017)

Plenary Session 1 - HIPAA and CLIA Considerations in Return of Results to Participants, Jackson Heart Study Workshop on Return of Results from Genetic and Genomic Studies, University of Mississippi Medical Center (April 4, 2017)

Keynote address, Critical Studies of Citizen Science, Department of Global Health and Social Medicine, King's College London (March 2, 2017)

Reflections on Solidarity as a Principle in Bioethics, Book Launch Event for Biomedicine and Beyond (Barbara Prainsack & Alena Buyx), Wallace Meeting Space, Covent Garden, London (March 1, 2017)

Special Challenges of Data Sharing and Access Under the Revised Common Rule, Seton Hall University (February 24, 2017)

Special Challenges of Data Sharing and Access in the 21st Century, NIH/NHGRI e-MERGE and CSER meeting, Bethesda, Md. (February 3, 2017)

How Patients are Creating the Future of Medicine: From Citizen Science to Precision Medicine, Dienard Memorial Lecture, University of Minnesota (December 6, 2016)

Regulation of Gene Editing Technology, Symposium on Health Care and Policy, Loyola University Chicago (October 28, 2016)

Consumer-driven Data Commons, Maurer School of Law, Indiana University (October 24, 2016)

Concepts of Patient Engagement, Luncheon address for staff of FDA's Center for Devices and Radiological Health (August 17, 2016)

Update on HIPAA Individual Access Rights and Impacts of the Genetic Information Nondiscrimination Act, Interpreta, Inc. Advisory Board Meeting (August 11, 2016)

Patient/Consumer Protection in the National Evaluation System for health Technology (NEST), Seminar: Using Real World Evidence for Regulatory Decision-Making and Patient Protection in the 21st Century, FDA Center for Devices and Radiological Health (August 16, 2016)

Participant, Design Workshop on Engaging Participants as Partners in Research, co-hosted by the White House Office of Science and Technology Policy and Stanford Medicine X (June 2, 2016) (*see* http://www.law.uh.edu/news/summer2016/0606Evans.asp and the "Navigating Privacy in Biomedical Research and Open Science" resource initiated at that meeting blog.jasonbobe.net/privacy-resources/

Oxford Union Debating Society, appearing in opposition to the motion, "This House Believes the Manipulation of Human DNA is an Ethical Necessity," Oxford University (May 26, 2016), *at* https://www.youtube.com/watch?v=O4uyXpBAmXQ .

Consumer-driven Data Commons, Health Data Exploration Project Annual Meeting, University of California at San Diego (May 18, 2016)

Panelist, Ethics and Policy Considerations, HGP/Write meeting Harvard Medical School (May 10, 2016), *at* https://www.youtube.com/watch?v=9xgm4U6E-CU (starting at 19 min., 30 sec.).

Big Data and Individual Autonomy in a Crowd, Petrie-Flom Annual Conference on Big Data, Health Law, and Bioethics, Harvard Law School (May 6, 2016), *at* https://vimeo.com/166555664 (starting at 5 min., 25 sec.).

Consumer-driven Data Commons, National Medical Device Evaluation System Planning Board Meeting (May 5, 2016)

Biotechnology: Getting the Legal Framework Right, Texas Center for Superconductivity, Meeting with Distinguished Visitors from National Chung Hsing University (April 7, 2016)

Consumer-driven Genomic Information Commons, Seminar on Ethical, Legal and Social Implications of Genetics, Center for Research on Ethical/Legal/Social Implications of Psychiatric, Neurologic & Behavioral Genetics, Department of Psychiatry, Columbia University Medical Center (March 14, 2016)

Building Sustainable Information Commons for Neurotechnology Research and Regulatory Science: Charting the Legal Pathways, NSF Industry/University Collaborative Research Center Planning Meeting (Tempe, March 10-11, 2016)

Participant, Roundtable on Privacy and Data Security, White House Precision Medicine Initiative Summit (Washington, February 25, 2016) (*see* http://www.law.uh.edu/news/spring2016/0229Evans.asp)

Big Data in Genomics and Precision Medicine, BioLaw Session, Association of American Law Schools Annual Meeting (New York, January 8, 2016)

Participant and Speaker, International Summit on Human Gene Editing, sponsored by the U.S. National Academy of Sciences, National Academy of Medicine, the Royal Society, and the Chinese Academy of Sciences (Washington, DC, December 1-3, 2015), *at* https://vimeo.com/album/3704161/video/149196322)

Current Controversies in Biotech and Law, University of Houston Health Law Speakers Series (November 4, 2015)

First Amendment Issues with FDA Regulation of Genomic Testing, FDLI/Georgetown Law School Symposium: Constitutional Challenges to the Regulation of Food, Drugs, Medical Devices, Cosmetics, and Tobacco Products (October 30, 2015)

Appearance before National Academy of Sciences, Engineering, and Medicine's ad hoc study committee on Federal Research Regulations and Reporting Requirements, in session at Rice University (October 29, 2015)

Big Data, Big Headaches: Cultivating Public Trust in an Age of Unconsented Access to Identifiable Data, University of Wisconsin Center for Predictive Computational Phenotyping Symposium: Big Data: Policy Meets Data Science (October 15, 2015)

Panelist, Genomics, University of California Santa Cruz DataLex Conference: Privacy, Big Data & The Law (October 13, 2015)

Participant, White House Champions of Change in Precision Medicine (July 8, 2014) (see http://www.law.uh.edu/news/summer2015/0715Evans.asp)

Participant, Precision Medicine Initiative Brainstorming Session, Harvard Medical School (June 25, 2015)

Reconciling Patient Access to Data with Quality Oversight, Precision Medicine Conference, Harvard Medical School (June 24, 2015)

Panelist, Engaging Patients: Building Trust and Support for Safety Surveillance Brookings Institution (June 23, 2015)

Individual Access to Health Data, Fifth International Summit on Health Information Privacy at Georgetown Law School (June 4, 2015)

Impact of Recent HIPAA-CLIA Amendments, Fifth International Summit on Health Information Privacy at Georgetown Law School (June 3, 2015)

Ownership of Data From Mobile and Wearable Health Devices, Health Data Exploration Project Meeting, U.C. San Diego *(May 13, 2015)*

2015 Distinguished Health Scholar Lecture Series, Seton Hall Law School (March 16 -19, 2015)

The Food and Drug Administration's Expanding Role in the Regulation of Genomic Research, National Aeronautics and Space Administration Genetics Meeting (February 24, 2015)

Participant, Robert Wood Johnson Foundation-funded Creative Commons Health Privacy and Data Sharing Workshop (February 18, 2015).

Recent Developments in Regulation of Genomic Testing, Baylor College of Medicine Genetics Seminar (February 2, 2015)

The Latest Legal Issues in Genomic Medicine, University of Washington Medical Genetics Colloquium (January 16, 2015)

Impact of CLIA-HIPAA Amendments and FDA Regulation on Return of Results, PRIM&R Advancing Ethical Research Conference (December 6, 2014)

Legally Engineering: Legal Aspects of Biotechnology, University of Houston Hispanic Professional Engineers Student Organization (December 4, 2014)

Privacy, Access, and Governance Issues Affecting Large Networked Health Information Systems,

University of Maryland Preeminence as an Innovator Fall Forum (October 28, 2014)

The Limits of FDA's Authority to Regulate Clinical Research Involving High-Throughput DNA Sequencing, Petrie-Flom and Food and Drug Law Institute Symposium: Emerging Issues in FDA Regulation (October 20, 2014)

FDA & Regulation of Genomic Sequencing: Implications for Return of Results, NIH Clinical Sequencing Exploratory Consortium Meeting, Bethesda, Md. (October 8, 2014)

Genomic Data Commons as a Patient Safety Imperative, Second Thematic Conference on Knowledge Commons: Governing Pooled Knowledge Resources, sponsored by the Engelberg Center on Innovation Law & Policy at New York University Law School (September 5, 2014)

Policy Issues in Next Generation Sequencing: Economic Regulation of Data Access, ASLME Health Law Professors' Conference (June 6, 2014)

Preventing Harm to Patients Who Know Too Much about Their Own Genomes, Petrie-Flom Annual Conference at Harvard Law School: Behavioral Economics, Law, and Health Policy, Harvard Law School (May 3, 2014)

Genomic Data Access after Myriad, Spring Advisory Council Dinner, Institute of Intellectual Property and Information Law (April 17, 2014)

Novel Liability Problems in Next Generation Sequencing, Roundtable on Personalized Medicine and Malpractice Liability, Arizona State University (April 4, 2014).

Participant, Workshop on Innovation in Evidence Development for Molecular Diagnostics, Scottsdale, Az. (April 3, 2014)

The Current Legal Framework of U.S. Privacy Protections, Institute of Medicine Public Workshop: Strategies for Responsible Sharing of Clinical Trial Data - Open Session (February 4, 2014)

Barriers to Genomic Communication, University of Houston Law Center Student Symposium on Recent Policy Developments in Biotechnology and Law (October 30, 2013)

Plenary speaker, First Amendment Issues with Access to Genetic Information, ASLME Health Law Professors' Conference (June 7, 2013)

Plenary speaker, Patients' Rights of Access to their Own Health Information, Third International Summit on Health Information Privacy at Georgetown Law School (June 6, 2013)

Regulating the Return of Results Without Triggering First Amendment Problems, National Institutes of Health/Clinical Sequencing Exploratory Research Consortium (Rockville, May 23, 2013)

The Future of Prospective Medicine After FDAAA, Annual Conference of the Petrie-Flom Center at Harvard Law School (May 3, 2013)

Nonconsensual Access to Data and Biospecimens for Research and Public Health, Greenwall Foundation Annual Meeting (May 1, 2013)

EMR Use for Postmarketing Medical Product Safety Surveillance, Case Western Reserve University Law School Symposium: Balancing Privacy, Autonomy and Scientific Progress: Patients' Rights and the Use of Electronic Medical Records for Non-Treatment Purposes (April 5, 2013)

Panelist, Privacy Law Panel, Careers in Information Law, University of Houston Intellectual Property Student Organization (Feb. 27, 2013)

Investigators' First Amendment Right to Return Results to Research Participants, University of Washington Division of Medical Genetics Seminars (February 15, 2013)

Client Misperceptions and the HIPAA Privacy Rule, Indiana University CLEAR Health Information Continuing Legal Education Program, Health Information and Ethical Representation (December 6, 2012)

Is Return of Individual Research Results Protected Speech Under the First Amendment? Greenwall Foundation Faculty Scholars Program (November 30, 2012)

Biospecimens and Medical Information: Ownership, Access, and Privacy, T.T. Chao Symposium, From Base Pairs to Bedside: What Happens When Genomics-Based Therapies Enter Our Clinics? (October 25, 2012)

Human Subjects Research Regulations: Statutory Constraints on Amendments to the Common Rule, ASLME Health Law Professors' Conference (June 8, 2012)

*In Search of Sound Policy on Nonconsensual Uses of Identifiable Health Data,,*Petrie-Flom Center, Harvard Law School, Annual Conference: The Future of Human Research Regulation (May 18, 2012)

Fallon Lecture, University of Chicago Center for Health and The Social Sciences (May 14, 2012)

Getting Past the "Terrible Twos" in Health Data Access, Benjamin Cardozo School of Law Symposium, Anonymity and Identity in the Information Age (May 4, 2012)

Informational Research for Medical Product Safety, Indiana University Robert H. McKinney School of Law Symposium, Imagining the Next Quarter Century of Health Care Law (April 12, 2012)

Data Access for 21st-century Biomedical Discovery, New York University School of Law Colloquium on Innovation Policy (February 23, 2012)

Nonconsensual Access to Identifiable Health Data, Association of American Law Schools 2012 Annual Meeting, Joint Session of the Sections on BioLaw and Defamation & Privacy (January 6, 2012)

The U.S. Food and Drug Administration Amendments Act of 2007 and its Impact on Clinical Translation of Pharmacogenomics, University of Toronto Health Law, Ethics and Policy Seminar Series (November 24, 2011)

Proposed Changes to the Common Rule, Texas Medical Center Council of Research Directors Meeting (August 24, 2011)

Panelist, *Control of Patient Data—Health Information Exchanges*, First International Summit on the Future of Health Privacy, Georgetown Law Center (June 13, 2011)

Public Use of Private Health Data, ASLME Health Law Professors' Conference (June 10 – 11, 2011)

Panelist, *Legal & Ethical Obligations*, Clinical Translation of Pharmacogenomics: Management of Incidental Findings and Related Issues, Duke Institute for Genome Sciences & Policy (June 8 – 9, 2011)

Work-in-Progress Presentation, *Data Ownership*, Greenwall Foundation Annual Meeting (May 23, 2011)

Panelist, *Planning Meeting for Summit on the Future of Health Privacy* sponsored by the LBJ School of Public Affairs and Patient Privacy Rights with support of the U.S. Army Telemedicine and Advanced Technology Research Center (November 19-20, 2010)

New Scholars Presentation, Greenwall Faculty Scholars Meeting (November 17 – 19, 2010)

Panelist, *Overview of the Legal & Regulatory Environment,* National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Panelist, *Alternatives or Supplements to Consent: Existing Regulatory Models,* National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Panelist, *Ethical Considerations*, National Institutes of Health-funded Critical Issues Workshop, Protecting Privacy in Health Research (August 10, 2010)

Ethical and Legal Issues in Pharmacogenetic Research and Application, Duke Clinical Research Institute Think Tank: Pharmacogenomics in Cardiovascular Disease: Balancing Scientific Promise with Clinical Reality (August 2, 2010)

Medical Device Legislation and FDA's Regulatory Authority: Legal Authorities to Develop Evidence and Manage Risks in the Postmarket Period for Drugs, 510(k) and PMA Devices, Institute of Medicine Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process (Closed Session, June 27, 2010)

Moving Pharmacogenomics into the Clinic, AARP Board of Directors/Management Retreat, Special Session on Personalized Medicine (June 10, 2010)

Ethical and Privacy Issues in Large Pharmacoepidemiological Data Networks, American Society of Law, Medicine & Ethics Health Law Professors' Conference (June 5, 2010)

Recent Developments in Genetic Screening and Medical Privacy, Annual Convention of TxCOEM, the Texas Chapter of the American College of Occupational and Environmental Medicine (May 21, 2010)

Panelist, *Public Policy Session*, American Society of Clinical Pharmacology and Therapeutics Annual Convention (March 19, 2010)

Pathways for Clinical Translation of Pharmacogenomics after FDAAA, Personalized Medicine in the Clinic, sponsored by Arizona State University/Mayo Clinic/AAAS/Food & Drug Law Institute (March 9, 2010)

Appropriate Human Subject Protections for Research Use of Sentinel System Data, Legal Issues in Active Medical Product Surveillance, convened by the Engelberg Center for Health Care Reform at the Brookings Institution with sponsorship of FDA (March 8, 2010)

Keynote Address: Health Technology, Privacy, and Process, Center for Cybersecurity Research Workshop: A Research Agenda for Privacy and Security of Healthcare Technologies (October 26-27, 2009)

Building Capacity Within Post-FDAAA Data Network Infrastructure, Institute of Medicine Forum on Drug Discovery, Development, and Translation, Community Update: Improving the Science of Drug Safety (September 2, 2009)

Update on Privacy and Governance Issues with FDA's 100-million-person Sentinel Data Network, American Society of Law, Medicine & Ethics Health Law Professors' Conference (June 5, 2009)

Ethical Framework for Pharmacogenomics Implementation (Including Econonomics), Mayo Clinic Pharmacogenetics Research Network Analysis Workshop and Scientific and Steering Committee Meetings (April 17, 2009)

Panelist, ABA Special Committee on Bioethics and the Law Roundtable on Hot Topics in Bioethics and Law, ABA Midyear Convention (February 14, 2009)

Panelist on Data Network Privacy Issues, FDA Public Workshop (Docket No. FDA-2008-N-0612) Sentinel Initiative: Structure, Function, and Scope (December 16, 2008)

Legal and Ethical Issues in Personalized Medicine: Making Therapies Safe for the Individual Patient Rather than the Average Patient, Houston Bar Association Health Law Section (September 10, 2008)

FDA's Sentinel System for Drug-safety Surveillance, Personalized Therapeutics Seminars, Indiana University School of Medicine (August 5, 2008)

Legal and Regulatory Issues Affecting Clinical Use of Personalized Medicine, American Association for Cancer Research, Translational Medicine 2008 Conference (July 21, 2008)

Pharma-provider Interactions and Ethical Guidelines, University of Houston Continuing Legal Education, Health Care Law (July 10, 2008)

FDA's Sentinel Initiative and Regulation of Medical Products with Predictive and Preventive Uses, American Society of Law, Medicine, and Ethics Annual Health Law Professors' Conference (June 7, 2008)

Ethical and Legal Challenges in Bioengineering, Rice University Lecture Series: New Developments in Bioengineering Technology (March 20, 2008)

Making Personalized Medicine Work: The Legal and Regulatory Paradigm Shift, New York Academy of Sciences, Predictive Toxicology Discussion Group Meeting on Toxicogenomics and Personalized Medicine (Feburary 4, 2008)

Cornerstones of Postmarket Considerations in Personalized Medicine: Label Updates, Surveillance, Clinical Practice, and Legal Liability (panelist), FDA/DIA 4th Annual Pharmacogenomics Workshop (December 11, 1007)

HIPAA Privacy Rule Reform Alternatives for Research Use of Human Biological Materials and Health Data, Roundtable on Personalized Medicine, Privacy, and Ethics (November 7, 2007)

Why Bioethics Fails to Produce Constitutional Rights, American Society of Law, Medicine, & Ethics/Saint Louis University Health Law Scholars Workshop (September 7, 2007)

Interactions Between Medical Product Manufacturers and Health-care Providers (Including Ethical Guidelines), University of Houston Continuing Legal Education, Health Care Law (Dallas, July 12, 2007 and Houston, July 19, 2007)

Use of Genetic Information to Guide Treatment Decisions, American Society of Law, Medicine, and Ethics 30th Annual Health Law Professors' Conference (June 1, 2007)

Individualized Medicine: Ethical Principles and Considerations. Individualized Therapy Lectures, Indiana University School of Medicine (April 13, 2007)

Protecting Patients from Invalid and Excessive Claims in Personalized Medicine, Personalized Medicine and Molecular Diagnostics: Legal, Regulatory, and Ethical Perspectives, Arizona State University (March 2, 2007)

Access to Human Biological Materials and Data in Cancer Research. American Society of Clinical Oncology HIPAA Workshop (February 23, 2007)

Regulatory Barriers to Clinical Introduction of Targeted Cancer Therapies, National Institute of General Medical Sciences, Pharmacogenetics Research Network—Consortium on Breast Cancer Pharmacogenomics Biannual Meeting (November 2, 2006)

Regulatory Barriers to Clinical Introduction of Genetically Targeted Drug Therapies, GenomeCanada International Conference, 2020 Vision: Variation and Function in the Genome (October 25, 2006)

Ethical and Regulatory Issues in New Product Development, Purdue University BIOMEDSHIP Program on Entrepreneurship in Biotechnology (April 20, 2006)

Genetic Studies in Hematological Malignancy: Ethical and Legal Considerations, Horizons in Diagnostics and Therapeutics: Developing Patient-Targeted Therapy, CME Corporate Friday Symposium at 47th American Society of Hematology Annual Meeting (December 9, 2005)

Intellectual Property and Regulatory Issues Affecting Targeted Therapies, Indiana University Department of Medicine, Presentation to Clinical Pharmacology Researchers (May 31, 2005)

Pharmacogenomics and its Implications for the Future of the Health Care Industry, Indiana University Medical Humanities Rounds (April 5, 2005)

Creating Incentives for Genomics Research to Improve Targeting of Therapies, Presentation to Eli Lilly Clinical Research Managerial Personnel (November 23, 2004)

Cultural and Economic Factors in Clinical Ethics, Presentation to Delegation of Japanese Oncologists, The University of Texas M.D. Anderson Cancer Center (May 19, 2004)

Should Prenatal Identification of Inherited Cancer Syndromes be Offered? Multidisciplinary Conference on Parenthood After Cancer: Today's Options and Tomorrow's Hopes, Sponsored by the National Cancer Institute (NCI), National Institute of Child Health and Development, Office of Women's Health at NCI, Office of Women's Health at the Department of Health and

Human Services, and the Lance Armstrong Foundation, held at The University of Texas M.D. Anderson Cancer Center (March 7, 2004)

Ethical Considerations of Genetic Testing and Screening for Cancer, Institutional Grand Rounds, The University of Texas M.D. Anderson Cancer Center (February, 2004)

Part II: Therapeutic Misconception and the Ethics of Phase I Clinical Trials, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (May 11, 2004) (with co-presenter Valerie Olson of Rice University Department of Anthropology)

Part I: Therapeutic Misconception and the Ethics of Phase I Clinical Trials, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (March 17, 2004) (with co-presenter Valerie Olson)

Emerging Issues in Clinical Application of Genetic Testing, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (January 16, 2004)

Professional Independence and the Ethics of Clinical Ethics Practice, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (December 9, 2003)

Patients' Decision-making Styles and Desire for Information When Making End-of-Life Decisions: Insights from Recent Empirical Studies, Clinical Ethics Didactic Presentation for M.D. Anderson Personnel (October 17, 2003)